K080509

510(k) SUMMARY of Safety and Effectiveness

(In accordance with SMDA of 1990 and pursuant with 21 CFR 807.92)

MAY - 5 2008

I. Applicant Information:

Date Prepared:	February 22, 2008
Submitter:	Medtronic, Inc.
Address:	Medtronic Cardiac Surgical Technologies 7601 Northland Drive N. Brooklyn Park, MN 55428-1088
Establishment Registration No.	2135394
Contact Person:	Julia Nelson Principal Regulatory Affairs Specialist
Telephone Number:	(763) 391-9183
Fax Number:	(763) 391-9259

II. Device Information:

Trade Name:	Cardioblate® Surgical Ablation System
Common Name:	Cardioblate® Surgical Ablation System, which consists of the Cardioblate® 68000 Generator (K060400) and the following ablation devices: ▪ Cardioblate® Monopolar Pens, Models 60813 and 60814 (K013392) ▪ Cardioblate® BP2 Surgical Ablation Device, Model 60831 (K060400) ▪ Cardioblate® LP Surgical Ablation Device, Model 60841 (K060400) ▪ Cardioblate® Gemini™ Surgical Ablation Device, Models 49260/049261 (K070311)
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification:	Class II, 21 CFR 878.4400
Product Code:	GEI

- Predicate Devices: Cardioblate® Monopolar Pen, Model 60813 and Model 60814 (K013392), and AtriCure® Bipolar System (K043579).
  Predicate Device Intended Uses:

  "The Medtronic Cardioblate® System is intended to ablate cardiac tissue during general surgery using radiofrequency energy." (K013392)

  "The Atricure Bipolar (Transpolar) System is intended for the ablation of cardiac tissue during surgery." (K043579)

Device Description: The Medtronic Cardioblate® Surgical Ablation System consists of a reusable radiofrequency generator which can be connected to hand-held monopolar or bipolar radiofrequency ablation devices. The ablation devices are sterile, single-use devices, operating in either monopolar or bipolar mode, that deliver the radiofrequency energy to the selected tissue.

Intended Use: *The Cardioblate® Surgical Ablation System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.*

Contraindications: The Cardioblate® Surgical Ablation System is contraindicated for patients that have active endocarditis at the time of surgery.

Ablation in a pool of blood (e.g., through a purse string suture on a beating heart). Effects of this type of ablation have not been studied.

Comparison to Predicate Device: The Cardioblate® Surgical Ablation System, including the generator and all ablation devices, has already been cleared by the FDA with the appropriate premarket notifications referenced above. No changes to the design or technology of the devices are contemplated in this submission. The sole change to the Cardioblate® devices is to clarify the intended tissue as "cardiac tissue" in accordance with the predicate devices (K013392 & K043579). The AtriCure Bipolar System (K0403579) was also device was identified as a predicate device with a similar indication.

Test Data: Verification and validation testing has demonstrated that all components of the Cardioblate Surgical Ablation System are safe and effective. Clinical data demonstrating the acute safety and ability of the device to create lines of electrical conduction block in the heart as assessed intraoperatively are provided to support the indication.

Summary: Based on the accumulated technical information, intended use, laboratory verification tests and clinical performance data provided, the Cardioblate System is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic, Inc.
Medtronic Cardiac Surgical Technologies
c/o Ms. Preeti Jain
Director of Regulatory Affairs
7601 Northland Drive
Minneapolis, MN 55428

MAY - 5 2008

Re: K080509
Cardioblate Surgical Ablation System, Models 60813 and 60814 Monopolar Pens, Model 60831 BP2, Model 60841 LP, and Models 49260/049261 Gemini
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II (two)
Product Code: OCL
Dated: February 22, 2008
Received: February 25, 2008

Dear Ms. Jain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K080509

Cardioblate® Surgical Ablation System, consisting of the Cardioblate® 68000 Generator (K060400) and the following ablation devices:

- Cardioblate® Monopolar Pens*, Models 60813 and 60814 (K013392)
- Cardioblate® BP2 Surgical Ablation Device, Model 60831 (K060400)
- Cardioblate® LP Surgical Ablation Device, Model 60841 (K060400)
- Cardioblate® Gemini™ Surgical Ablation Device, Models 49260/049261 (K070311)

Indications for use:

The Medtronic Cardioblate® System is intended to ablate cardiac tissue during general surgery using radiofrequency energy.

* These devices are already labeled with the proposed indication statement.

Prescription Use ___x___ **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

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